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Case 8569

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Application of	:	
L. R. ROBINSON ET AL.	:	Confirmation No. 5928
Serial No. 09/867,235	:	Group Art Unit 1617
Filed May 29, 2001	:	Examiner Lauren Q. Wells

For: METHODS OF ENHANCING DELIVERY OF OIL-SOLUBLE SKIN CARE ACTIVES

DECLARATION UNDER 37 CFR §1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, the undersigned, do hereby declare and say:

THAT, all statements set forth are of my own knowledge true and that all statements made on information and belief are believed to be true:

THAT, I, LARRY RICHARD ROBINSON, hold the degree of Doctor of Philosophy in Organic Chemistry from Iowa State University;

THAT, I have been employed by the Beauty Care organization of The Procter & Gamble Company from June 28, 1987 to the present;

THAT, in my position in the Beauty Care Division, Research & Development Department of The Procter & Gamble Company, I did undertake to prepare:

A skin care penetration study, conducted via a standard Franz cell skin penetration study using a similar protocol as disclosed in *Curr. Probl. Dermatol.*, Vol 7, pp. 58-68 (Karger, Basal 1978): The Finite Dose Technique as a Valid *in vitro* Model for the Study of Percutaneous Absorption in Man, by Thomas J. Franz, in which dermal skin penetration of active compounds were determined.

In Experiment 1, penetration of an oil-soluble active, farnesol, in a delivery vehicle containing water, silicone and silicone elastomers was compared to penetration in a delivery vehicle consisting of an oil-in-water emulsion and no elastomer.

In Experiment 2, penetration of a water-soluble active, niacinamide, was compared in separate delivery vehicles similar to those used in Experiment 1.

The following results were obtained:

ACTIVE	VEHICLE	Mean $\mu g/cm^2$ penetrated in 24 hours
Experiment 1: Oil Soluble Active (Farnesol)		
3% Farnesol	Water in Silicone + Elastomers	31.21*
3% Farnesol	Mineral Oil in Water	17.52
Experiment 2: Water Soluble Active (Niacinamide)		
3.5% Niacinamide	Water in Silicone + Elastomers	2.32*
3.5% Niacinamide	Mineral Oil in Water	3.89

The asterisk (*) indicates that the results are significantly different at $p \leq 0.10$.

THAT, I am one of the co-inventors named on the above-identified patent application.

THAT, I am familiar with this invention's prior art, including Rouquet et al. (EP 0908175).

THAT, the present application relates to a skin care composition containing silicone elastomers for enhanced delivery of oil-soluble skin care actives, and to a method of enhancing delivery of oil-soluble skin care actives by administering said composition to the skin of a mammal in need thereof.

I, LARRY RICHARD ROBINSON , further say: Based on my professional experience, it is my professional opinion that this data indicate that delivery of the oil-soluble skin care active is significantly enhanced when delivered from a vehicle containing water, silicone and silicone elastomer relative to the delivery of the same oil soluble skin care active from a vehicle that does not contain a silicone elastomer. In addition, this enhancement in delivery of an active is specific for oil soluble actives as evidenced by the significant *decrease* in skin delivery of a water soluble active in a water, silicone and silicone elastomer vehicle relative to a vehicle that does not contain silicone elastomer.

Further Declarant Sayeth Not.

This declaration is made with the knowledge that willful false statement and the like are punishable by fine or imprisonment, or both, under 18 USC §1001 and may jeopardize the validity of the application or any patent issuing from it.

Larry Richard Robinson

September 20, 2004

Date